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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,170	10/02/2003	Ross J. Hamel	SYNT-0108	6800
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/676,170

Applicant(s)

HAMEL, ROSS J.

Examiner

HAO D. MAI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-7, 9-17, 19, 21, 23, 25-36, 40, 41 and 44-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1, 4-7, 9-17, 19, 21, 23, 25-36, 40, 41 and 44-59 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "recess adapted to receive a portion of the surgical instrument, the recess having an inner surface adapted to clamp at least a portion of the surgical instrument to the second member" (claim 59) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact

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terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 59 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 59 recites "the clamping member comprises a recess adapted to receive a portion of the surgical instrument, the recess having an inner surface adapted to clamp at least a portion of the surgical instrument to the second member". It is unclear exactly where is the recess on the clamping member 44 as shown in Figure 4, and how the recess' inner surface would clamp a portion of the surgical instrument to the second member (sleeve 42). Note that a through-hole (48) for receiving and clamping a surgical instrument is already claimed in independent claim 52.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 4-7, 9-17, 19, 21, 23, and 25-30, are rejected under 35 U.S.C. 102(b) as being anticipated by Koteles et al. (5,938,592).

Regarding claim 1, Koteles et al. disclose surgical retractor (Fig. 2) comprising: a handle 22 having a longitudinal axis, proximal and distal ends, and a longitudinally elongated outer surface that is capable of being held by an operator; a first coupling mechanism 32 coupled to the proximal end of the handle; and a blade member 46 having proximal and distal ends. The coupling mechanism comprising a knob 42 having a bore, wherein at least a portion of the knob is disposed within the handle, and wherein the knob is rotatable about the longitudinal axis of the handle. The blade member 46 comprises a coupling element (shaft 24) being configured and dimensioned to be received in the bore of the knob; wherein rotation of the knob in a first direction causes shaft 24 to advance into the bore of the knob.

As to claim 4-6, the coupling element 24 is a shaft having outer threads 44 to mate with the inner threads of the knob's bore; and the handle is shown to have an opening to receive knob 42. As to claims 7 and 9, Figure 7A shows a retractor blade having an opening (between extension 98, 100) at the distal end of the blade that is configured and dimensioned to be capable of allowing a surgical tool or an orthopedic to pass there through. As to claims 10-13, the blade has a structure that is capable of stabilizing itself against bone; and Figs. 7A-7C show the blade having a hook-shape with a C-shape and/or an L-shape.

As to claim 14, note the either of the second coupling 32 or the pivot clamp 54 can be a second coupling mechanism locating on the handle capable of coupling a second surgical instrument to the handle. As to claims 15-17, the second surgical instrument and any limitations thereof are not given patentable because the second surgical instrument is only inferentially claimed.

As to claims 19, 21, and 23-27, Koteles et al. disclose a second coupling mechanism 50 comprising a coupling member (snap connection 58) contacting a second member (pivot clamp 54), wherein the coupling member 58 and the second member 54 are operatively associated to fix a second surgical instrument (rake 52) with respect to the handle. The coupling

member/snap connection 58 is telescopically received within the handle and comprises a recess (formed by hook 64) capable of receiving a portion of rake 52 (Fig. 2).

As to claim 28, Koteles et al. disclose another surgical instrument such as one of the retractor blades shown in Figs. 7A-8B having a coupling element (shaft 104) that is configured and dimensioned to connect interchangeably with the first coupling mechanism. As to claim 30, note a second handle (connector hub 70) transverse to the longitudinal axis (Fig. 2).

6. Claims 1, 4-7, 9-13, and 30, are further rejected under 35 U.S.C. 102(e) as being anticipated by Scirica et al. (2002/0035313 A1).

Regarding claim 1, Scirica et al. disclose a surgical retractor (Figs. 11, 19) comprising: a handle 210 having a longitudinal axis, proximal and distal ends, and a longitudinally elongated outer surface capable of being held by an operator; a first coupling mechanism 214 coupled to the proximal end of the handle 210; and a blade member 216 having proximal and distal ends (Fig. 11). The coupling mechanism 214 comprises a knob/dial 240 having a bore, wherein at least a portion of the knob 240 is disposed in the handle, and wherein the knob is rotatable about the longitudinal axis of the handle (Fig. 19). The blade member comprises a coupling element (cable 226) that is received in the bore of knob 240, and rotation of the knob in a first direction D causes the coupling element/cable 29 to advance into the bore of the knob (Figs. 19, 29; paragraph 63). Note that rotating dial 240 would move the handle assembly 212 in the direction "E", thus indirectly moving or stretching the cable 226 through the bore of dial 240 (Figs. 19, 29; paragraph 63).

As to claim 4, note that the coupling element is a shaft/cable 226. As to claims 7,9, and 10, Figure 24 shows blade 216 having an aperture (between the two extensions 216a, 216b) capable of allowing a surgical tool or an orthopedic implant to pass through; and the blade has a structure that is capable of stabilizing itself against bone. As to claims 11-13, note that the

blade generally has a hook-shape, comprising a C-shape formed by the two extensions 216a, 216b (Fig. 24); wherein each extension 216 has an L-shape (Fig. 29). As to claim 30, note the second handle (frame 220) transverse to the longitudinal axis of handle 210 (Fig. 11).

7. Claims 52-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Furnish et al. (6,254,535).

Regarding claim 52, Furnish et al. disclose a retractor 10 comprising: a handle 76/78/72 having a longitudinal axis, a proximal end (towards 72), a distal end (towards 76), and an opening 73; a first coupling mechanism 74 coupled to the proximal end of the handle, wherein the first coupling mechanism is rotatable about the longitudinal axis of the handle (Fig. 1). The retractor further comprises a second coupling mechanism 50 (best seen in Figure 5) disposed on a backside of the handle proximate the proximal end of the handle. The coupling mechanism 50 having a through-hole (bore 58) and at least a portion of the through-hole is axially moveable within the opening 73 of the handle; wherein the through-hole/bore 58 is sized and configured to be capable of receiving a surgical instrument (e.g. shaft 80 or 44). The retractor further comprises a blade 20 (best seen in Fig. 6) having a proximal end and a distal end. The blade member comprises a coupling element (slide segment 22) connecting with the first coupling mechanism 74.

As to claim 53, the surgical instrument and any structures thereof are not given any patentable weight since the surgical instrument was only inferentially claimed. As to claims 54, the second coupling mechanism is a clamping member 50 telescopically received within the handle at handle's opening 73 (best seen in Fig. 1). As to claims 55-58, note that there is a second member between the clamping member 50 and the handle's portion 72, so that the clamping member 50 is not in direct contact with the handle. The clamping member 50 and the

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second member are operatively associated with each other to fix the surgical instrument with respect to the handle.

8. Claims 52-54 are further rejected under 35 U.S.C. 102(b) as being anticipated by Wells (5,904,650).

Wells discloses a retractor 10 comprising: a handle 40 having a longitudinal axis, proximal and distal ends, and an opening 46 (best seen in Fig. 3); a first coupling mechanism 60 coupled to the proximal end of the handle, wherein the first coupling mechanism is rotatable about the longitudinal axis of the handle; and a blade member (receptacle 30) comprises a coupling element (ball 50) connecting to the first coupling mechanism (Figs. 1-3). The retractor further comprises a second coupling mechanism 28 disposed on a backside of the handle proximate the proximal end of the handle. The second coupling mechanism having a through-hole, at least a portion of which is axially moveable within opening 46, wherein the through-hole of the second coupling mechanism is sized and configured so that it is capable of receiving a surgical instrument (as demonstrated by shaft 52 and ball 50).

As to claim 53, the surgical instrument and any structures thereof are not given any patentable weight since the surgical instrument was only inferentially claimed. As to claim 54, note that the second coupling mechanism 28 is a clamping member telescopically received within the handle.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 31-36, 40-41, and 44-47, are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg (5,558,622) in view of any one of Scirica et al. and Koteles et al.

Greenberg discloses a method for treating a bone that includes providing the surgical retractor, making an incision in the soft tissue and elevating the tissue off the bone (Fig. 17, S, SI, OI and M), passing a portion of the blade through the incision and retracting the tissue (Fig. 17, OI), circumventing at least part of the bone with a portion of the blade and stabilizing a portion of the blade on the bone (Fig. 17, #'s 58, 59, and M), and performing a surgical procedure on the bone (Fig. 17, D and P). Additionally, part of the procedure involves using a surgical tool (D) to pass an orthopedic implant (P) through the cavity (SI) and the aperture of the blade (Fig. 17, #60). The surgical instrument can be a drill (and therefore a burr) (Column 6, lines 22-27) inserted through a drill guide or cannula (Column 2, lines 14-19). The implant secured to the bone can be a bone fastener or a screw (Column 6, lines 22-27) and used in an orthognathic procedure to fixate a fracture (Claim 32) on a bone segment (mandible) that comprises a condylar neck and a ramus.

Greenberg however fails to disclose the retractor as claimed. Scirica and Koteles each discloses the claimed retractor as detailed above with respect to claim 1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute Greenberg's retractor with the retractor of Scirica or Koteles as a suitable alternative retractor while still obtaining the same and or predictable results.

11. **Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg in view of any one of Scirica and Koteles, as applied to claim 44 above, and further in view of Swaniger (US 4,769,011).**

Greenberg in combination of one of Scirica and Koteles, disclose the claimed methods as described above, with the exception of using a grafting procedure. Swaniger discloses methods for mandibular surgery that are well known in the art including a grafting procedure (Column 1, lines 21-24), using a biocompatible bone filler material (Column 1, lines 30-38), and the use of a syringe to implant the bone filler material (Column 2, lines 10-13). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform a grafting procedure as taught by Swaniger in order to augment the alveolar ridge.

Response to Arguments

12. Applicant's arguments with respect to the newly amended claims filed 04/23/2008 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated

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from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAO D. MAI whose telephone number is (571)270-3002. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hao D Mai/
Examiner, Art Unit 3732

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732